REMARKS

In the Office Action of September 11, 2001, Claims 1 - 27 were rejected. No claim was allowed. In response, Claims 1 - 16 and 19 - 27 are canceled without prejudice or disclaimer Claims 17 - 18 are amended and new Claims 28 - 43 are added to the application. Reexamination and reconsideration are respectfully requested in view of the foregoing amendments and the following remarks.

Restriction Requirement

The Office Action contained a restriction requirement even though all the claims were considered on the merits. Applicants hereby elect Group II, Claims 17 - 24, drawn to methods of use. Accordingly, Claims 17 and 18 are amended and new Claims 28 - 43, which relate to subject matter within Group II, are added.

Rejection of Claims 1 - 27 under 35 U.S.C. §112, first paragraph

Claims 1 - 27 were rejected under 35 U.S.C. §112, first paragraph, on the alleged grounds that the specification, while being enabling for specific proteins listed in the specification and the cholesterol lowering effect of the complex, does not provide enablement for generic "protein" and "lipid improving agent or a corresponding method".

In response, Claims 17 and 18 are amended so that the term "protein" is limited to plant protein. It has been shown that plant proteins have the effect of improving lipid metabolism, especially in lowering cholesterol content, as described in Fig. 1 at page 19 of Journal of Food Science, 40, 18–23 (1975). Thus, a person skilled in the art would have used not only wheat protein or soybean protein but also plant proteins in general to prepare the protein/phospholipid complex or protein hydrolyzate/phospholipid of the present invention for improving lipid metabolism without undue experimentation.

Regarding the allegation of the Examiner that "lipid metabolism" includes numerous processes, and that the instant specification is not adequately enabling to anything other than the cholesterol lowering effect of the complex, the term "improving lipid metabolism" in claim 17 is changed to "treating or preventing a disease selected from fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction", and these terms are supported by the description at page 6, lines 24 to 29 of this specification. It has been known that improving lipid metabolism, for example lowering cholesterol or lipid level in serum or liver, can be fully applied for treating or preventing a disease selected from fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction (see e.g. Harrison's Principles of

International Medicine, Tenth edition, pages 547 to 559). Further, the Declaration of Samoshi Nagaoka dated March 5, 2002 shows that the complex of claimed invention prevents both serum and liver from accumulating not only cholesterol but also total-lipids, triacylglycerol and phospholipid.

Thus, the claims drawn to the method for treating or preventing a disease selected from fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction of the animal by administering the complex of claimed invention have broad basis of support in the specification.

Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, are thereby overcome.

Rejection of Claims 1 - 27 under 35 U.S.C. §112, second paragraph

Claims 1 - 27 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner alleges that it is unclear what the term "complex" is intended to convey, what enzyme modifies lecithin, what is meant by functional food, what is meant by improving, and how the complex is recovered as recited in Claims 25 and 26.

In response, Claims 1 - 16 and 19 - 27 are canceled and the rejection is traversed as it may apply to Claims 17 and 18 as amended and to new Claims 28 - 43.

Regarding the term "complex", it is defined in amended Claim 17 and 18 as the complex containing "20–50% of bound phospholipid", as described at page 3, lines 18 to 19 of the specification, and the "bound phospholipid" is clearly defined as the "phospholipid which remains bound to a protein after being treated with a nonpolar organic solvent such as petroleum ether" at page 2, line 35 to page 3, line 2 of the specification.

Regarding the term "enzyme-modified lecithin", this term is limited in new claims 29, 30, 36 and 37 to "enzyme–modified lecithin obtainable by treating phospholipase" which is supported at page 2, lines 30 of the specification.

Regarding the term "functional food" in claim 13, this claim is canceled.

Regarding the term "improving" and "metabolism" in claim 17, the term in the amended claim 17 is clearly defined as "treating or preventing a disease selected from fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction".

Accordingly, it is respectfully submitted that all of the rejections under 35 U.S.C. §112, second paragraph, are thereby overcome as they may apply to Claims 17 and 18 as amended and new Claims 28 - 43.

Rejection of Claims 19 - 24 under 35 U.S.C. §101

Claims 19 - 24 were rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. In particular, the Examiner alleges that the Examiner alleges that Claims 19 - 24 do not set forth any steps involved in a method or process.

In response, Claims 19 - 24 are canceled without prejudice or disclaimer. Accordingly, it is respectfully submitted that this rejection is moot.

Rejection of Claims 1 - 13, 15 and 16 under 35 U.S.C. §102(b) over Dictionary of Modern Medicine (1994);Rejection of Claims 1 - 13 and 15 - 24 under 35 U.S.C. §102(b) over JP 61 152632; Rejection of Claims 1 - 13 and 15 - 24 under 35 U.S.C. §102(b) over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988)

Claims 1 - 13, 15 and 16 were rejected under 35 U.S.C. §102(b) as anticipated by Dictionary of Modern Medicine (1994). Claims 1 - 13 and 15 - 24 were rejected under 35 U.S.C. §102(b) as anticipated by JP 61 152632. Claims 1 - 13 and 15 - 24 were rejected under 35 U.S.C. §102(b) as anticipated by Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988).

In response, Claims 1 - 16 and 19 - 27 are canceled without prejudice or disclaimer. Accordingly, it is respectfully submitted that these rejections are moot.

Rejection of Claims 14 and 21 - 27 under 35 U.S.C. §103(a) over JP 61 152632 or Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988)

Claims 14 and 21 - 27 were rejected under 35 U.S.C. §103(a) as obvious over JP 61 152632 or Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988).

In response, Claims 14 and 21 - 27 are canceled without prejudice or disclaimer. Accordingly, it is respectfully submitted that this rejection is moot.

Rejection of Claims 1 - 27 under 35 U.S.C. §103(a) over Williams in combination with either Sirtori or Nagaoka

Claims 1 - 27 were rejected under 35 U.S.C. §103(a) as obvious over Williams (Perspectives in Biology and Medicine, 1984) in combination with either Sirtori (Ann. Nutr. Metab. 1985) or Nagaoka (Agric. Bio. Chem (1991). The Examiner alleges that Williams teaches the effectiveness of phospholipids in cholesterol removal and that Sirtori and Nagaoka teach the effectiveness of proteins in altering the lipid metabolism. The Examiner takes the position that it would have been obvious to combine the phospholipids of Williams with the proteins of Sirtori or Nagaoka with the expectation of obtaining at least an additive effect.

This rejection is traversed as it may apply to Claims 17 and 18 as amended and to new Claims 28 - 43. Amended Claim 17 relates to "a method for treating or preventing a disease

selected from fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction". Claim 18 relates to a method of improving cholesterol metabolism. Claim 34 relates to "a method of lowering cholesterol or lipid level". Claim 35 relates to a method for producing food and feed. All of these claims require the use of a plant protein/phospholipid complex or plant protein hydrolyzate/phospholipid complex containing 20—50 wt% of bound phospholipid.

Williams teaches the effectiveness of phospholipids in cholesterol removal and Sirtori and Nagaoka teach the effectiveness of proteins in altering lipid metabolism.

However, even if it is known that a plant protein, its hydrolyzate and a phospholipid individually contribute to improving lipid metabolism, a person skilled in the art would not expect that a synergistic effect of improving lipid metabolism is obtained when the complex obtained by binding phospholipid to the plant protein or its hydrolyzate is administered to an animal.

In this regard, Tables 2, 4, 6 and 8 of the present specification and the Declaration of Satoshi Nagaoka clearly show that the complex of the claimed invention has the unexpected effect of improving lipid metabolism, especially lowering cholesterol or lipid level in serum and liver, compared with the plant protein or the simple mixture of plant protein and phospholipid.

Further, a person skilled in the art would not expect the remarkable effect of improving lipid metabolism that is achieved when a complex that contains 20–50 wt% of bound phospholipid is administered to an animal.

In this regard, the Declaration of Goro Hori dated March 1, 2002 shows that the amount of bound phospholipid should be in from 20 to 50 wt% in order to obtain the maximum performance of the protein/phospholipid complex for improving cholesterol metabolism.

Thus, such an unexpectedly improved effect of the plant protein/phospholipid or plant protein hydrolyzate/phospholipid complex containing 20–50 wt% of bound phospholipid according to the claimed method is not disclosed or suggested in these references.

Accordingly, it is respectfully submitted that any case of obviousness is overcome by the showing herein, and that the rejection under 35 U.S.C. §103(a) over Williams, Sirtori or Nagaoka for obviousness is thereby overcome.

Conclusion

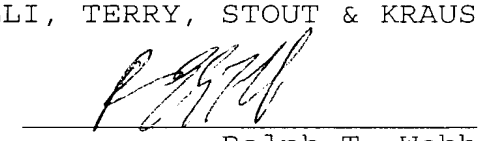
In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 17 and 18 and new claims 28 to 43 are in condition for allowance. Favorable reconsideration is respectfully requested.

Should the Examiner believe that anything further is necessary to place this application in condition for

allowance, the Examiner is requested to contact applicants' undersigned attorney at the telephone number listed below.

Kindly charge any additional fees due, or credit overpayment of fees, to Deposit Account No. 01-2135 (506.35379CC2).

Respectfully submitted,
ANTONELLI, TERRY, STOUT & KRAUS



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Attachments:
Declaration Pursuant 37 CFR 1.132 of Goro Hori
Declaration Pursuant 37 CFR 1.132 of Satoshi Nagaoka

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IN THE CLAIMS

17. (amended) A method for ~~improving the lipid metabolism~~ treating or preventing a disease selected from the group consisting of fatty liver, hypertension, hyperlipidemia, arteriosclerosis, obesity, diabetes and myocardial infarction of an animal which comprises administering to the animal ~~the complex according to claim 1~~ a protein/phospholipid complex or protein hydrolyzate/phospholipid complex containing 20 - 50 wt% of bound phospholipid, wherein said protein is derived from a plant.

18. (amended) A method for improving the cholesterol metabolism of an animal which comprises administering to the animal the complex ~~according to claim 1~~ a protein/phospholipid complex or protein hydrolyzate/phospholipid complex containing 20 - 50 wt% of bound phospholipid, wherein said protein is derived from a plant.